50. (New) A method to enhance the expression of a polynucleotide in a host cell, comprising: contacting a host cell comprising a recombinant AAV vector corresponding to the vector of claim 19, with a composition comprising a further recombinant AAV vector comprising a polynucleotide segment which encodes a polypeptide, in an amount which enhances expression of the polynucleotide.

51. (New) A method to enhance the expression of a polynucleotide in a host cell, comprising: contacting a host cell with a recombinant AAV vector corresponding to the vector of claim 19 and a further recombinant AAV vector comprising a polynucleotide segment which encodes a polypeptide, in an amount which enhances expression of the polynucleotide in the cell.

52. (New) The method of claim 49 or 50 wherein the composition further comprises a delivery vehicle.

53. (New) The method of claim 52 wherein the delivery vehicle is a pharmaceutically acceptable carrier.

54. (New) The method of claim 49, 50 or 51 wherein heterologous transcriptional regulatory element in the recombinant AAV corresponding to the vector of claim 19 is a promoter.

Remarks

Claims 49-54 are added. The pending claims are claims 1-54.

Support for amended claim 19 is found in originally-filed claim 19 and at page 5, lines 1-13, page 6, line 29-page 7, line 6, and page 11, line 28-page 12, line 3 of the specification.

Support for new claims 49-54 is found in originally-filed claims 1-3, 8-9 and 25-26.

In response to the Restriction Requirement, Applicant provisionally elects, with traverse, the invention of Group VII (claims 19-20 and 23, and new claims 49-55, which are dependent on claim 19) directed to a recombinant adeno-associated viral vector comprising at least one

heterologous transcriptional regulatory element functional in a host cell, which vector regulates, in the host cell, expression of a therapeutic gene in a second recombinant adeno-associated viral vector, wherein the heterologous transcriptional regulatory element is a promoter, and methods which employ such a vector. Reconsideration and withdrawal of the Restriction Requirement, in view of the remarks herein, is respectfully requested.

The Restriction Requirement is traversed on the basis that the inventions are so closely related within the context of the disclosure of the application. Claims directed to a recombinant adeno-associated viral (rAAV) vector comprising at least one heterologous transcriptional regulatory element functional in a host cell, which vector regulates, in the host cell, expression of a therapeutic gene in a second rAAV vector, wherein the heterologous transcriptional regulatory element is a promoter, and methods which employ such a vector (claims 19-20, 23 and 49-55; Group VII) are clearly related to claims directed to a rAAV vector comprising at least one heterologous transcriptional regulatory element functional in a host cell, which vector regulates, in the host cell, expression of a therapeutic gene in a second rAAV vector, wherein the heterologous transcriptional regulatory element is an enhancer (claims 19, 21 and 23; Group VIII); claims directed to a composition comprising at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, and wherein one of the rAAVs contains a promoter linked to an open reading frame (claims 1, 4-7, 9-11, and 46-47; Group II); claims directed to a composition comprising at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the rAAV, wherein one of the rAAVs contains an enhancer (claims 1, 8 and 46-47; Group III); claims directed to a method to transfer recombinant DNAs to a host cell comprising contacting the host cell with at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, wherein one of the rAAVs contains a promoter linked to an open reading frame (claims 26-31, 33, 35, 37, and 48; Group XI); a method to transfer recombinant DNAs to a host cell comprising contacting the host cell with at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, wherein one of the rAAVs contains an enhancer (claims 26-27, 32, 34, and 48; Group XII); and a method to transfer recombinant DNAs to a host cell comprising contacting the host cell with at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV,

wherein one of the rAAVs contains an enhancer and the other rAAV contains a promoter (claims 26-27, 32, 34, 36, and 48; Group XIII).

In particular, claims directed to a rAAV vector comprising at least one heterologous transcriptional regulatory element functional in a host cell, which vector regulates, in the host cell, expression of a therapeutic gene in a second rAAV vector, wherein the heterologous transcriptional regulatory element is a promoter, and methods which employ such a vector (claims 19-20, 23 and 49-55; Group VII) are clearly related to claims directed to a composition comprising at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, and wherein one of the rAAVs contains a promoter linked to an open reading frame (claims 1, 4-7, 9-11, and 46-47; Group II); claims directed to a method to transfer recombinant DNAs to a host cell comprising contacting the host cell with at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, wherein one of the rAAVs contains a promoter linked to an open reading frame (claims 26-31, 33, 35, 37, and 48; Group XI); and a method to transfer recombinant DNAs to a host cell comprising contacting the host cell with at least two rAAVs, in which one rAAV comprises sequences that are different than the sequences in the other rAAV, wherein one of the rAAVs contains an enhancer and the other rAAV contains a promoter (claims 26-27, 32, 34, 36, and 48; Group XIII).

The Restriction Requirement is also traversed on the basis that Restriction Requirements are optional in all cases. M.P.E.P. § 803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it arguably may include claims to distinct or independent inventions. M.P.E.P. § 803. Moreover, it is submitted that Applicant should not be required to incur the additional costs associated with the filing of multiple divisional applications in order to obtain protection for the claimed subject matter. Due to the relatedness of the subject matter of the claims in Groups VII, II, III, VIII, XI, XII, and XIII, the claims in Groups VII, II, III, VIII, XI, XII, and XIII can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner as those claims are directed to subject matter which includes a rAAV which comprises a transcriptional regulatory element which is internal to the ITRs. Moreover, due to the relatedness of the subject matter of the claims in Groups VII, II, XI, and XIII, the claims in Groups VII, II, XI, and XIII

can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner as those claims are directed to subject matter which includes a rAAV that comprises a promoter which is internal to the ITRs.

Further, evidence that the claims in at least Groups VII-VIII can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner is provided in the Restriction Requirement as those claims are in the same class and subclass (class 435 and subclass 320.1) for search purposes.

In the event the Examiner does not group claims 49-54 with the claims in Group VII, Applicant's Representatives respectfully request rejoinder of claims 49-54 with the claims in Group VII upon a notice of allowance for the claims in Group VII.

Thus, the Restriction Requirement is properly traversed. Accordingly, reconsideration and withdrawal of the Restriction Requirement is respectfully requested.

The Examiner is invited to contact Applicant's Representatives at the number given below if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this day of November 26th 2002.

Candis B. Buending
Name

_____
Signature